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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,779	06/28/2000	John H. Griffin	SCRIP1180-3	1406

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

606,779

Applicant(s)

GRIFFIN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## P r i d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 3/22/02 & 9/4/02.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 2-15 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 2-15 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Pri rity under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 1 ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other \_\_\_\_\_

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The amendment filed on 3/22/02 and 9/9/02 have been entered. Claims 2-15 are pending and under examination.

The examiner concurs with applicant's urgings set forth in Paper 12 (filed 9/9/02) that the incorporation by reference of the disclosures of prior applications is not new matter. The preliminary amendment, submitted with the filing papers, that likewise incorporates these by reference has been noted.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Due to applicant's cancellation of claim 1, the 101 double patenting rejection of record has been withdrawn. However, in lieu thereof, the following new obviousness-type double patenting rejection is stated.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 5,834,223. Although the conflicting claims are not identical, they are not patentably distinct from each other because the broader claims of issued patent 5,834,223 encompass the subject matter of the narrower claims of the instant application.

More specifically, the "subject" of issued claim 1 must be considered as encompassing all of the kinds of patients that were specifically mentioned in the specification, including "patients taking oral anticoagulants" (instant specification page 2, line 22 and page 3, lines 8-9 corresponding to col. 2 lines 15-16 and 28-29). Thus the limitation regarding the subject, as recited in the preamble of instant claim 2, is encompassed by issued claim 1.

Also the limitations regarding the specific ranges of calcium and APC concentrations present in assay step a) of instant claim 2, were clearly encompassed by what is recited in issued claim 1, since these ranges were taught as preferred. See instant page 8, lines, 7 and 10 corresponding to col. 5, lines 24 and 28-29.

Instant claims 4-8, 11-12 and 14 correspond to issued claims 4-13.

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Instant claims 9-10 13 and 15 each recite specific limitations upon concentrations and/or reagents used. These limitations are all taught at instant specification pages 7-8 or cols. 4-5 and hence encompassed by the issued claims.

Due to the fact that all of what is presently claimed is encompassed by the issued claims, a terminal disclaimer is required in order to provide for common ownership of Pat. 5,834,223 and any patent issuing from the instant application.

Due to applicant's presentation of claim 2, in lieu of claim 1, the prior art rejections of record based upon Dahlback (WO 94/17415) or Dahlback et al., have been withdrawn. It is noted that neither reference teaches obtaining test samples from patients on oral anticoagulant therapy.

It is also noted that the calcium concentration recited in step [a] of claim 2 is outside of the concentration that would result upon dilution of the APC-CaCl<sub>2</sub> mixture disclosed by Dahlback at page 21, lines 15-31.

Claims 2-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Sun et al. (Blood, 83,3120, 1994). Sun et al. show the instant assay that dilutes a sample in Factor V deficient plasma. They teach that this assay may be used to assay for APC resistance with samples from patients on oral anticoagulant therapy, such as with heparin (page 3124, col. 1, last full para.) They teach the instantly recited concentrations of calcium and of APC (page 3120, col. 2, second para.). Aspects of dependent claims 2 and 7-15 are also taught therein, the

*This is true for Dahlback  
PNAS*

*This  
is  
true*

*WO 94/17415*

*This is wrong for  
WO 94/17415 Vit K*

*antagonist  
at page 17 mention  
oral drugs like  
warfarin*

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limitations of claims 4-6 are taught at page 2124 , col. 1, first full para.

Applicant may address this rejection by a declaration filed according to In re Katz 215 USPQ 14.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3076. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

December 3, 2002

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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